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C mpl t if Known							
Application Number	10/603,214						
Filing Date	06-25-2003						
First Named Inventor	BARKER						
Group Art Unit							
Examiner Name							
Attorney Docket Number	USAV2001/0077 - US - NP						

	-		U.S. PATENT DOCL	JMENTS	
Examiner Initials*	Cite No.1	U.S. Patent Docume Kind Co Number (if know	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1/2		2003/0140923 A1	TAYLOR et al	07-31-2003	Figures Appear
双	<u> </u>	3,442,686	JONES	05-06-1969	
<u> </u>		4,145,001	WEYENBERG et al.	03-20-1979	
		4,150,744	FENNIMORE	04-24-1979	
		4,332,845	NAWATA et al.	06-01-1982	
	<u> </u>	4,407,897	FARRELL et al	10-04-1983	
		4,449,632	MARUSIAK Jr.	05-22-1984	
		4,528,234	KAIHO et al	07-09-1985	
		4,657,133	KOMATSU et al.	04-14-1987	
\bot	<u> </u>	4,667,814	WAKAMATSU et al.	05-26-1987	
		4,702,963	PHILLIPS et al.	10-27-1987	· · · · · · · · · · · · · · · · · · ·
		4,971,196	KITAMURA et al	11-20-1990	
		5,221,566	TOKOH et al.	06-22-1993	
		5,300,138	FISCHER et a.	04-05-1994	
		5,322,161	SHICHMAN et al.	06-21-1994	
		5,567,488	ALLEN et al.	10-22-1996	
		5,657,748	BRAITHWAITE	08-19-1997	
1		5,911,937	HEKAL	06-15-1999	
У		6,050,400	TASKIS et al.	04-18-2000	
113		6,103,141	INCORVIA et al.	08-15-2000	

				FOR	EIGN PATENT DOCUMENT	rs		_
Examiner Initials*	No.1	Office	Foreign Patent Do Number4	Cument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T0
47		JP	58-148759		NAOE et al.	09-03-1983		
43		wo	93/11938		WILFONG et al.	06-24-1993		
73		wo	03/043905		BARKER et al	05-30-2003		Ė
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			SCLOSURE	Filing Date	06-25-2003		
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Sheet	2	of	3	Attorney Docket Number	USAV2001/0077 - US - NP		

				U.S. PATENT DOCL	JMENTS	
Examiner Initials	Cite No.1	U.S. Patent I Number	Cocument Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
737		6,306,503 B1		TSAI M L	10-23-2001	
702		6,315,112 B1		GARRILL et al.	11-13-2001	
37		6,316,521 B1		DISCH et al.	11-13-2001	
					 	
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FOREIGN PATENT DOCUMENTS												
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INFU	KMAII	ON DIS	CLOSURE	Filing Date	06-25-2003	
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Sheet	3	of	3	Attorney Docket Number	USAV2001/0077 - US - NP	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
J>		, Guidance for Industry-Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), October, 1998					
D7		, Guidance for Industry-Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics, U.S. Department of Health and Human Services, Food and Drug Administration; Center for Drug Evaluation and REsearch (CDER) and Center for Biologics Evaluation and Research (CBER), June 1997					
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